

K971048

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Applicant Name & Address:** Bio-Vascular, Inc., 2575 University Ave., St. Paul, MN 55114-1024

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**Common or Usual Name:** Peri-Strips Dry - Staple Line Reinforcement

**Device Classification Name:** Surgical Patch

**Substantial Equivalence:** Peri-Strips - Strips Configuration K942583 &  
Peri-Strips - Sleeve Configuration K940205

**Device Description:** Dehydrated bovine pericardium strips cross-linked with glutaraldehyde. Affixed to the stapler forks with PSD Gel, a hydrogel.

**Statement of Intended Use:**

intended to reinforce staple lines during lung and bronchus resections including; pneumonectomy, pneumoreduction, pneumectomy, segmentectomies (segmental resections) wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections and other lung incisions and excisions of lung and bronchus.

**Summary/Comparison of Technological Characteristics:**

Peri-Strips Dry, Peri-Strips Sleeves and Peri-Strips Strips are derived from the same material, Supple Peri-Guard. The dimensions (length, width, and thickness) of the Peri-Strips Dry pericardium strips fall within the same range as the current Peri-Strips products.

The manufacturing processes for all three Peri-Strips products are the same with the following exceptions:

- there are no tyvek sleeves sutured to the pericardium strips as is done with the Peri-Strips sleeves product
- the tissue is vacuum dried at the end of the process, then precision cut.

The staplers intended for use with the Peri-Strips Dry product are a subset of the current Peri-Strip products.

Peri-Strips Dry is irradiation sterilized, the Peri-Strips products are chemically sterilized.

The current Peri-Strips products are attached to the stapler forks with sutures or the tyvek sleeves. The Peri-Strips Dry product utilizes a hydrogel (PSD Gel) to affix the strips to the stapler forks.

**Summary:** The basis for the product design is the same, bovine pericardium cross-linked with glutaraldehyde. The greatest differences between the Peri-Strips Dry and our current products is in the how the product is sterilized, packaged and affixed to the stapler forks. Each of these changes were made in an effort to enhance the product and make it easier for the physician to use. Moreover, the testing conducted, including the animal implants, indicate that the product performs in a manner equivalent to our current product.